



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

THERMO FISHER SCIENTIFIC  
C/O CYNTHIA KNAPP  
DIRECTOR OF CLINICAL OPERATIONS  
1 THERMO FISHER WAY  
OAKWOOD VILLAGE OH 44146

February 27, 2014

Re: K133773

Trade/Device Name: Sensititre 18-24 hour MIC Susceptibility System  
Regulation Number: 21 CFR 866.1640  
Regulation Name: Antimicrobial susceptibility test powder  
Regulatory Class: II  
Product Code: JWY, LRG, LTT  
Dated: December 12, 2013  
Received: December 13, 2013

Dear Ms. Knapp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 **Uwe Scherf -S** for

Sally A. Hojvat, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K133773

Device Name: The Sensititre® 18 - 24 hour MIC Susceptibility System Test Panel with Meropenem (0.004 - 8µg/mL)

### Indications for Use:

The Sensititre® 18 - 24 hour MIC or Breakpoint Susceptibility System is an in vitro diagnostic product for clinical susceptibility testing of non-fastidious isolates.

This 510(k) is for the removal of the limitation for the ability to detect resistance for Meropenem (0.004 - 8µg/mL) and Enterobacteriaceae and for the addition of the newly approved breakpoints (S≤1, I=2, R≥4) on the Sensititre® 18 - 24 hour MIC panel for testing Gram negative isolates.

The approved primary, "Indications for Use" and clinical significance for Enterobacteriaceae is for the following species:

*Escherichia coli*  
*Klebsiella pneumoniae*  
*Proteus mirabilis*

### In vitro data, without clinical correlation is provided for:

*Aeromonas hydrophila*  
*Citrobacter koseri* (formerly *diversus*)  
*Citrobacter freundii*  
*Enterobacter cloacae*  
*Hafnia alvei*  
*Klebsiella oxytoca*  
*Morganella morganii*  
*Proteus vulgaris*  
*Serratia marcescens*

Prescription Use   X    
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use         
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Ribhi Shawar -  
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